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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 44426.1-2024

**Assistive products for tissue integrity when lying down - Part 1:
General requirements**

躺卧保护组织完整性的辅助器具 第1部分：一般要求
(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is part 1 of GB/T 44426 "Assistive devices for protecting tissue integrity while lying down". GB/T 44426 has been published.

The following parts.

--- Part 1: General requirements.

This document is modified to adopt ISO 20342-1:2022 "Assistive devices for protecting tissue integrity during lying down - Part 1: General requirements".

This document has the following structural adjustments compared to ISO 20342-1:2022.

---4.6~4.8 corresponds to 4.7~4.9 of ISO 20342-1:2022.

The technical differences between this document and ISO 20342-1:2022 and their reasons

are as follows.

--- Modified the term "rehabilitation aids/assistive devices" (see Chapter 3, Chapter 3 of ISO 20342-1:2022), and ISO 9999:2022 is aligned;

--- Modified the general requirements (see 4.1, 4.1 of ISO 20342-1:2022), deleted the item "Clinical evaluation" (see ISO 20342-1.

2022) and the related terms "clinical evaluation" (see 3.8 of ISO 20342-1:2022) and "clinical study" (see 3.9 of ISO 20342-1:2022) and the normative reference document ISO 14155 to adapt to the current status of my country's rehabilitation assistive device industry;

--- Replace IEC 62366-1 with the normative reference YY/T 1474 (see 4.4.1), and replace IEC 60601-1-6 with YY/T 9706.106 (see 4.4.1), ISO 20417 replaces EN1041 (see 5.1.1, 5.1.7), YY/T 0466.1 replaces ISO 15223-1 (see 5.1.7), GB/T 3785.1 replaces IEC 61672-1 (see 5.4, 5.5), GB/T 3768 replaces ISO 3746 (see 5.4, 5.5), GB/T 16404 replaces ISO 9614-1 (see 5.4, 5.5), GB/T 17248.3 replaces ISO 11202 (see 5.5), GB/T 3785.2 replaces IEC 61672-2 (see 5.5), YY9706.108 replaces IEC 60601-1-8 (see 5.6), GB/T 5169.16 replaces IEC 60695-11-10 (see 6.3), YY9706.252 replaces IEC 60601-2-52 (see 7.1), GB/T 42062 replaces ISO 14971 (see 7.3), GB 9706.1-2020 replaces IEC 60601-1:2005 AMD1.2012 AMD2.2020 (see 7.6, 7.7, 8.1), YY9706.235 replaces IEC 60601-2-35 (see 7.7), YY9706.102 replaces IEC 60601-1-2 (see 8.1, 8.2.1, 8.2.3), YY9706.111 replaces IEC 60601-1-11 (see 8.1), GB 4824 replaces CISPR11 (see 8.2.2), GB 17625.1 replaces IEC 61000-3-2 (see 8.2.2), GB/T 17625.2 replaces IEC 61000-3-3 (see 8.2.2), GB/T 17626.3 replaces IEC 61000-4-3 (see 8.2.3), GB/T 17626.8 replaces IEC 61000-4-8 (see 8.2.4), GB/T 4208 replaces IEC 60529 (see 8.3), GB/T 16754 replaces ISO 13850 (see 8.6), GB/T 16886.1 replaces ISO 10993-1 (see 9.1), YY/T 0771.1 replaces ISO 22442-1 (see 9.2) to adapt to my country's technical conditions.

The following editorial changes were made to this document.

--- Deleted the footnotes (see 5.1.8, 5.6, 7.7 of ISO 20342-1:2022);

--- Deleted informative appendices A, B, C and notes referring to the contents of the appendix in the entries (see 4.1, 5.1.6, 6.1, 8.2.4, 9.1).

Introduction

In different application environments (such as institutional care and home care), assistive devices for preserving tissue integrity (APT_I) have been used in maintaining body position, preventing it plays a significant role in preventing and treating pressure injuries (pressure sores). ISO plans to develop a series of standards to promote the quality improvement of APT_I.

There are three standards, namely ISO 20342-1, ISO 20342-7, and ISO 20342-10, and some other standards are still under development.

GB/T 44426 "Assistive devices for protecting tissue integrity when lying down" aims to improve the quality and reliability of APTI and provide a reference for its production and inspection it is intended to provide a basis for its use and is composed of 9 parts.

--- Part 1: General requirements. The purpose is to specify lying protection organizations in different application environments (such as institutional care, home care) General requirements and test methods for assistive devices that protect tissue integrity (APTI) and assistive devices that guide lying and protect tissue integrity the production and testing of pressure tools (APTI) plays an important role in protecting user safety and preventing and treating pressure injuries.

--- Part 2: Microclimate. The purpose is to provide microclimate characteristics such as APTI heat dissipation and water vapor dissipation under specified test conditions.

Test method.

--- Part 3: Strength and impact. The purpose is to specify the requirements and procedures for APTI strength and impact tests.

--- Part 4: Durability. The purpose is to specify the test method for APTI durability.

--- Part 5: Resistance to cleaning and disinfection. The purpose is to provide tests to evaluate the resistance of APTI to cleaning and disinfection by liquid chemical disinfectants method.

--- Part 6: Horizontal stiffness. The purpose is to specify the test method for APTI horizontal stiffness.

--- Part 7: Properties, characteristics and performance of foams. The purpose is to provide terminology used by manufacturers and laboratories to quantify foam properties.

and common test methods.

--- Part 8: Pressure distribution. The purpose is to describe the ability of APTI to redistribute pressure and to specify the test method for pressure distribution.

methods, reporting of results, and the clinical significance of the results.

--- Part 10: Cleaning, disinfection and care guidance for polyurethane covers. The purpose is to provide guidance on cleaning, disinfection and care A practical guide to APTI polyurethane covers.

Assistive devices for lying down to protect tissue integrity Part 1: General requirements

1 Scope

This document specifies assistive devices for preserving tissue integrity (APTI) for lying down in different application settings (e.g. institutional care, home care).